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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,632	01/14/2004	Bianca Baroli	0492611-0520	4661
24280 7590 01/10/2007 CHOATE, HALL & STEWART LLP TWO INTERNATIONAL PLACE BOSTON, MA 02110			EXAMINER BARNHART, LORA ELIZABETH	
			ART UNIT	PAPER NUMBER
			1651	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
31 DAYS		01/10/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/757,632	BAROLI ET AL.	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-81 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-81 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

### **DETAILED ACTION**

Claims 1-81 are currently pending.

#### ***Election/Restrictions***

This application contains claims directed to the following patentably distinct species:

Uses of system: (a) drug delivery, (b) tissue engineering, (c) diagnostic purposes, (d) detoxification, and (e) substance removal, as in claims 2-5, for example; elect ONE.

Insoluble materials: (f) gelatin, (g) collagen, (h) natural polymer and (i) synthetic polymer, as in claims 6-9, 33-36, and 62- 65, for example; elect ONE.

Bioactive materials: (j) drug, (k) enzyme, (l) protein, and (m) growth factor, as in claims 10-13 and 37-40, for example; elect ONE.

Drugs: (n) calcifying agent, (o) antibiotic, (p) anticancer agent, (q) anti-inflammatory agent, (r) cytokine, (s) matrix metalloproteinase, (t) cell mediator, (u) inhibitor, (v) antimitotic agent, (w) alkylating agent, (x) immunomodulator, (y) anti-hypertensive, (z) analgesic, (a') antifungal, (b') antibody, (c') vaccine, (d') hormone, (e') cardiovascular agent, (f') respiratory agent, (g') sympathomimetic agent, (h') cholinomimetic agent, (i') adrenergic, (j') adrenergic neuron blocking agent, (k') antimuscarinic agent, (l') antispasmodic agent, (m') skeletal muscle relaxant, (n') diuretic, (o') uterine agent, (p') antimigrane agent, (q') local anesthetic, (r') antiepileptic, (s') psychopharmacological agent, (t') histamine, (u') antihistamine, (v') central nervous system stimulant, (w') antineoplastic agent, (x') immunosuppressive agent, (y') vitamin, nutrient, (z') antimicrobial agent not comprised in antibiotics, (a'') antiviral agent, (b'')

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parasiticide, and (c'') diagnostic agent, as in claims 14, 41, and 66, for example; elect ONE if both species (a) and species (j) are elected.

Compatible substrates: (d'') sugar, (e'') polysaccharide, (f'') glycolipid, (g'') glycosaminoglycan, (h'') lipid, (i'') amino acid, (j'') peptide, (k'') polypeptide, (l'') protein, (m'') amine, (n'') lipo-proteic molecule, (o'') polyol, (p'') gum, (q'') wax, (r'') antioxidant, (s'') anti-reductant, (t'') buffering agent, (u'') inorganic salt, (v'') organic salt, (w'') radical scavenger, (x'') diluent, (y'') cryoprotectant, (z'') natural polymer, (a''') synthetic polymer, (b''') glycine, (c''') sodium glutamate, (d''') proline, (e''')  $\alpha$ -alanine, (f''')  $\beta$ -alanine, (g''') lysine-HCL, (h''') 4-hydroxyproline, (i''') betaine, (j''') trimethylamine N-oxide, (k''') ammonium, (l''') sodium, (m''') magnesium sulfate, (n''') potassium phosphate, (o''') sodium fluoride, (p''') sodium acetate, (q''') sodium polyethylene, (r''') sodium caprylate, (s''') propionate, (t''') lactate, (u''') succinate, (v''') mannitol, (w''') lactose, (x''') sorbitol, (y''') sucrose, (z''') inositol, (a''') dicalcium phosphate, (b''') calcium sulfate, (c''') cellulose, (d''') hydroxypropylmethylcellulose, (e''') kaolin, (f''') sodium chloride, and (g''') starch, as in claims 16-20, 43-47, and 68-72, for example; elect ONE.

Binders: (h''') starch, (i''') gelatin, (j''') sugar, (k''') natural gum, (l''') synthetic gum, (m''') polyethylene glycol, (n''') ethylcellulose, (o''') wax, (p''') water, (q''') alcohols, (r''') amylase, (s''') methacrylate, (t''') methyl methacrylate copolymer, (u''') sucrose, (v''') glucose, (w''') dextrose, (x''') molasses, (y''') lactose, (z''') acacia, (a''') sodium alginate, (b''') extract of Irish moss, (c''') panwar gum, (d''') ghatti gum, (e''') mucilage of isapol husks, (f''') carboxymethylcellulose, (g''') methylcellulose, (h''') hydroxypropyl methylcellulose, (i''') hydroxypropyl cellulose, (j''') ethyl cellulose, (k''')

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polyvinylpyrrolidone, (l''''') Veegum, and (m''''') larch arabogalactan, as in claims 22-24, 49-51, and 74-76, for example; elect ONE.

Plasticizers: (n''''') glycerin, (o''''') propylene glycol, (p''''') polyethylene glycol, (q''''') triacetin, (r''''') acetylated monoglyceride, (s''''') citrate ester, and (t''''') phthalate ester, as in claims 26, 53, and 78, for example; elect ONE.

Disaggregants: (u''''') starch, (v''''') clay, (w''''') cellulose, (x''''') algin, (y''''') gum, (z''''') cross-linked natural polymer, (a''''') cross-linked synthetic polymer, (b''''') Veegum HV, (c''''') methylcellulose, (d''''') agar, (e''''') bentonite, (f''''') cellulose, (g''''') wood product, (h''''') natural sponge, (i''''') cation-exchange resin, (j''''') alginic acid, (k''''') guar gum, (l''''') citrus pulp, (m''''') carboxymethylcellulose, and (n''''') sodium lauryl sulfate, as in claims 28, 55, and 80, for example; elect ONE.

Manners of shielding: (o''''') granulation, (p''''') spray drying, (q''''') spray chilling, (r''''') lyophilization, (s''''') coating vapor deposition, (t''''') compression, (u''''') microencapsulation, (v''''') coating, (w''''') subcoating, (x''''') sealing, (y''''') coacervation, (z''''') suspension, (a''''') precipitation, (b''''') cogelation, (c''''') gelation, (d''''') inclusion in pre-formed delivering systems, (e''''') inclusion in matrix, (f''''') inclusion in micromatrix, and (g''''') evaporation, as in claims 29, 56, and 81, for example; elect ONE.

Photopolymerization means: (h''''') UV radiation, (i''''') blue-light radiation, (j''''') visible radiation, and (k''''') radiation produced by light emitting diodes technology, as in claims 31, 59, and 61, for example; elect ONE.

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Drug delivery systems: (l''''') capsules, (m''''') tablets, (n''''') powders, (o''''') granules, (p''''') pills, (q''''') pellets, (r''''') reservoir devices, (s''''') matrix devices, (t''''') microparticles, (u''''') microspheres, (v''''') nanoparticles, (w''''') nanospheres, (x''''') microcapsules, (y''''') nano-capsules, (z''''') liposomes, (a''''') lyophilized systems, (b''''') osmotic systems, (c''''') emulsions, (d''''') microemulsions, (e''''') gels, (f''''') gelified systems, (g''''') implants, (h''''') implantable mems, (i''''') implantable microdiagnostic devices, (j''''') implantable nano-diagnostic devices, (k''''') solid lipid nanoparticles, (l''''') chip, (m''''') microchips, (n''''') microarrays, (o''''') environmental sensitive systems, (p''''') immune system sensitive systems, (q''''') dissolution-controlled systems, (r''''') swellable systems, (s''''') osmotic pumps, (t''''') osmotic micro-pumps, (u''''') magnetic systems, (v''''') cyclodextrins, (w''''') human cells, (x''''') animal cells, (y''''') stem cells, (z''''') immortalized cells, and (a''''') engineered cells, as in claim 57; elect ONE.

The species are distinct because none is rendered obvious by the others in its group and because the disclosure does not connect them by any design, operation, or effect. See M.P.E.P. § 806.04(b). A requirement for restriction is permissible if there is a patentable difference between the species as claimed and there would be a serious burden on the examiner if restriction is not required. See M.P.E.P. § 808.01(a). In this case, considering enablement, utility, and description issues for each claimed species, as well as conducting a thorough search of the prior art for each and every combination embodied by the present claims, would pose a serious burden to the examiner.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. **That is, applicant should elect ONE embodiment in which ALL variables are particularly pointed out.** Failure to elect ONE from each group as directed above, even if the election be traversed, will constitute a noncompliant reply. Currently, claims 2-14, 16-20, 22-24, 26, 28, 29, 31, 33-41, 43-47, 49-51, 53, 55-57, 59, 61-66, 68-72, 74-76, 78, 80, and 81 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

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The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lora E Barnhart

leb



Leon B. Lankford, Jr.  
Primary Examiner  
AU 1651